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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/868,533

09/21/2001

Stuart Neville Farrow

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04/10/2007

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B475

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EXAMINER

MONDESI, ROBERT B

ART UNIT

PAPER NUMBER

1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/868,533	<b>Applicant(s)</b> FARROW ET AL.	
	<b>Examiner</b> Robert B. Mondesi	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on January 22, 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

This Office action is in response to the amendment filed January 22, 2007.

**Claims 21-26** are presently pending and under examination.

### ***Withdrawal of Objections and Rejections***

The objections and rejections not explicitly restated below are withdrawn due to applicants' response in amendment filed January 22, 2007.

### ***Maintenance of rejections***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

**Claims 21-26** remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants are correct in assuming that **claims 21-26** were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants are also correct in stating that the enablement rejection issue is with regards to SEQ ID NO: 1 and 2, and not SEQ ID NO: 6.

The above rejection was explained in the previous Office Action.

***Response to applicants' arguments***

In regards to the rejection of **claims 21-26** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, applicants assert that The claimed invention is a method of screening compounds to identify whether the compounds decrease binding between the recited polypeptide and its B-cell receptor. The claims do not recite the compounds themselves. Applicants submit that one of ordinary skill in the art, given the disclosure of the present specification, could make and use the claimed screening method.

Applicants submit further that the disclosure in the prior art or specification of compounds tested and shown to inhibit binding is not needed to enable the claimed screening method. What must be enabled is the claimed invention; as binding of the polypeptides to B-cells has been shown, and methods of detecting such binding are known in the art, one of ordinary skill in the art could readily use the claimed assay to screen a multitude of-test compounds.

Applicants' arguments have been considered but have not been found persuasive. The decrease in binding of a polypeptide and its receptor is not an adequate for activity of a compound that would satisfy the enablement requirements under 35 U.S.C, first paragraph. Applicants have not connected or provided a nexus of the screening assay with a "real life activity". Just because a compound interferes with the binding of a polypeptide and its receptor it does not mean that the said compound has any measurable or assayable activity. At the heart of the problem of the claims of the invention, with regards to the above indicated rejection, is the fact that the binding of

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the polypeptide comprising SEQ ID NO: 1 or 2 and its receptor is not associated with any real measurable activity. If the mentioned compound is to be assayed or screened, then it is prudent that there should be a measurable or observable activity that is associated with the screening assay. Applicants have not shown to a person skill in the art, as to what assayable activity is associated with the binding of the mentioned polypeptide and its receptor. The applicants, also as a consequence, have not shown to a person skill in the art, what activity the assayed compound is to decrease. Without having a measurable activity, a person skill in the art would not know how to use a method of screening a compound that affects the binding of a polypeptide ligand and its receptor. Applicants should amend claim 21 in order to include a measurable activity that is associated with the binding of the polypeptide comprising SEQ ID NO: and the B cells receptor.

***New Objection(s) and Rejection(s)***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 21** rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al.

United States Patent No. 6,716,576.

Applicants have amended claim 21 to include the phrase "an amino acid sequence" of SEQ ID NO: 1; this in effected has broadened the breadth and scope of the claim to the extent that any fragment of SEQ ID NO: 1 is now encompassed by the claim.

Yu et al. teach a method of screening for a compound that involves an amino acid sequence of SEQ ID NO: 1 (column 9, lines 64-68 through column 10, lines 1-26 and see, printout of sequence alignment performed by STIC)

Applicants can easily overcome the rejection by simply amending "an amino acid sequence" to "the amino acid sequence".

Thus Yu et al. teach all the elements of **claim 21** and these claims are anticipated under 35 USC 102(b).

### ***Conclusion***

No claims are allowed.

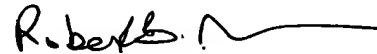
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi  
Examiner  
Art Unit 1652



3-2-2007